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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/719,055 | 11/21/2003 | John M. Williams | 2478.2018-001 | 9135 |

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,055

Applicant(s)

WILLIAMS, JOHN M.

Examiner

Shirley V. Gembeh

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 12, 2004, has been considered.

Claim Rejections - 35 USC § 112

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 -4 where Rⁿ is a substituted or unsubstituted alkyl/aralkyl/aryl group is indefinite connoting no information as to what substituents are used, therefore, examiner suggests using substituents selected from groups according to those disclosed in the specification.

Substituted and optionally substituted cycloalkyl, aryl, C₁-C₄ aralkyl and cycloalkylalkyl groups, surely, they do not all carry the same properties, therefore examiner suggests applicant clearly states the compounds or groups that are considered and use the above suggestion supra for the substituted Rⁿ.

Claim 3 recites the limitation "heteroaralkyl" in line 3. There is insufficient antecedent basis for this limitation in the claim 2. As claimed, -NR₅R₆ when taken together do not form an aromatic heterocyclic group.

Claim 4 recites the limitation "cycloalkyl, C₁-C₄ aralkyl and cycloalkylalkyl groups in line 3. There is insufficient antecedent basis for this limitation in claim 2.

Art Unit: 1614

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

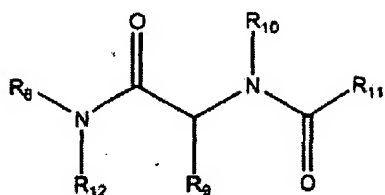
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-26 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-20 of copending Application No. 10/719,701. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claims are drawn to a composition and method of inhibiting rejection of a transplant organ composition, using formula

Art Unit: 1614



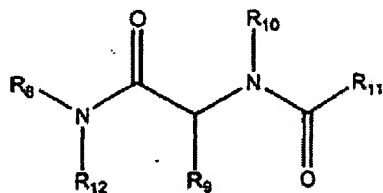
in the instant claim with rapamycin or CD40L. The only difference between the instant application and the co-pending application is in the instant claim adjuvant therapy is used while the co-pending claims treat the condition with only the compound of formula I. Thus the claims of the instant application are within the scope of the co-pending application.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-8 and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sneddon et al., WO 01/87849.

Sneddon discloses current claims 1 and 2, a method of inhibiting tissue transplant, as graft versus host disease, at page 14, line 30, administering the



compound of formula I,

wherein, R₈ represents

hydrogen, at page 82, line 7, R₁ represent is R₉ in the reference is a

substituted/unsubstituted aryl, line 10; R₂ =R₁₀ is optionally substituted alkyl, line 13,

Art Unit: 1614

and where it is an alkyl group substituted with $-NR_5R_6$, at page 98, line 18, R_3 represents R_{11} is a substituted alkyl, line 16; $R_4 = R_{12}$ is a substituted alkyl.

Sneddon discloses current claims 4-8, wherein, $R_4 = R_{12}$ is a substituted aryl group at page 82, line 7, and as in current claim 5 wherein R_4 is a substituted phenyl group at page 97 line 2, and a benzyl as in current claim 6. Sneddon also discloses current claims 7 and 8, wherein $R_1 = R_9$ is C_1-C_4 is either a substituted aryl/alkyl group at page 82 line 10, claim 9 a substituted aryl group, and an optionally substituted phenyl group as in claim 10. Claim 1 is disclosed at page, 52 table 1 compound 1, subsequently the reference anticipates claims 11-23.

Sneddon also discloses administering the compound of current claims 24-26 at page 86 to a patient with graft versus host disease at page 14 line 30.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVS
SVG
10/27/05

Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**